SynchroMedical
The interphalangeal reference

REF : DT007-016-EN Rev12

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Single registration number : FR-MF-000001222

Chassieu, September 13th 2024

EU DECLARATION OF CONFORMITY

ADSM, represented by Luigi BIVI, President, hereby certifies, under his sole responsibility, that the following medical devices comply with all the provisions of Medical Device Regulation dated April, 5th 2017 and with provisions from the Public Health Code, section 5, book number II, 1st Title (article R665-1 et al., if applicable).

STERILEBITZ							
Reference	**Designation**	**Class**	**Classification rule**	**UDI-DI code**	**CND code**	**BUDI-DI code**	**Indication**
110.25.000-SB	STERILE KIRSCHNER WIRE WITH THREADED TIP	IIb	Annex VIII, Chapter III Rule 8	03701091007257	P091203	037010910DT007KWS TEPH	These medical devices are only indicated for patient with a body mass superior or equal to 10kg. **Kirschner wires (transient use)** These devices are indicated for: - temporary stabilization of bone fragments during surgery - as a guidance system for product-specific medical devices **Kirschner wires (long-term use)** These devices are indicated for long-term fixation of bone segments in order to obtain bone fusion, both in a percutaneous or open surgical approach. **Guide wires (transient use)** These devices are indicated as a guidance system for product-specific medical devices
299.20.150-SB				03701091007127			
02.01362.116-SB				03701091007103			
290.06.070-SB	STERILE KIRSCHNER WIRE WITH TROCAR TIP			03701091007080		037010910DT007KWSTEPH	
290.08.070-SB				03701091007066			
290.10.150-SB				03701091007042			
290.12.150-SB				03701091007028			
290.14.150-SB				03701091007004			
290.14.280-SB				03701091006984			
290.16.150-SB				03701091006960			
290.16.280-SB				03701091006946			
290.18.150-SB				03701091006922			
290.18.280-SB				03701091006908			
290.20.150-SB				03701091006885			
290.20.280-SB				03701091006861			
290.25.150-SB				03701091006847			
290.25.280-SB				03701091006823			
290.25.310-SB				03701091006809			
2810-01-175-SB	STERILE PARTIAL THREADED GUIDE WIRE	IIa	Annex VIII, Chapter III Rule 6	03701091006786	L091001	03701091 0DT007G WSTEN5	
00-2490-450-32-SB				03701091006762			

STERILEBITZ							
Reference	**Designation**	**Class**	**Classification rule**	**UDI-DI code**	**CND code**	**BUDI-DI code**	**Indication**
110.25.000-R	KIRSCHNER WIRE WITH THREADED TIP	IIb	Annex VIII, Chapter III Rule 8	03701091007264	P091203	037010910DT007KWN ONSTEUZ	These medical devices are only indicated for patient with a body mass superior or equal to 10kg. **Kirschner wires (transient use)** These devices are indicated for: - temporary stabilization of bone fragments during surgery - as a guidance system for product-specific medical devices **Kirschner wires (long-term use)** These devices are indicated for long-term fixation of bone segments in order to obtain bone fusion, both in a percutaneous or open surgical approach. **Guide wires (transient use)** These devices are indicated as a guidance system for product-specific medical devices
299.20.150-R				03701091007110			
02.01362.116-R				03701091007097			
290.06.070-R	KIRSCHNER WIRE WITH TROCAR TIP			03701091007073		037010910DT007KWNONSTEUZ	
290.08.070-R				03701091007059			
290.10.150-R				03701091007035			
290.12.150-R				03701091007011			
290.14.150-R				03701091006991			
290.14.280-R				03701091006977			
290.16.150-R				03701091006953			
290.16.280-R				03701091006939			
290.18.150-R				03701091006915			
290.18.280-R				03701091006892			
290.20.150-R				03701091006878			
290.20.280-R				03701091006854			
290.25.150-R				03701091006830			
290.25.280-R				03701091006816			
290.25.310-R				03701091006793			
2810-01-175-R	PARTIAL THREADED GUIDE WIRE	IIa	Annex VIII, Chapter III Rule 6	03701091006779	L091001	037010910 DT007GWN ONSTESM	
00-2490-450-32-R				03701091006755			

This declaration is based on:

- The technical file DT007 demonstrating compliance with general safety and performance requirements of MDR 2017/745
- The full quality assurance system certification (certificate N° SX 1551305-1) delivered by TÜV RHEINLAND LGA PRODUCTS GmbH (Notified body number 0197), Tillystraße 2, 90431 Nürnberg, GERMANY.
- MDR 2017/745 EC certificate (certificate N°HZ 1551305-1) delivered by TÜV RHEINLAND LGA PRODUCTS GmbH (Notified body number 0197), Tillystraße 2, 90431 Nürnberg, GERMANY,

as per conformity assessment procedure of Annex IX, Chapter I, Sections 2 and 3 and Chapter III.

This for the period of validity of the certificate until: 2026/10/12.

NB: this declaration is only valid in combination with a specific batch release document.

Luigi BIVI
President

DocuSigned by:
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Lise ROLLY TAYMANS
PRRC

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Lise Taymans
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